

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RL-447WO	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/IB2004/003487	International filing date (day/month/year) 22/10/2004	(Earliest) Priority Date (day/month/year) 22/10/2003
Applicant RANBAXY LABORATORIES LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

PROCESSES FOR THE PREPARATION OF AMORPHOUS ROSUVASTATIN CALCIUM

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

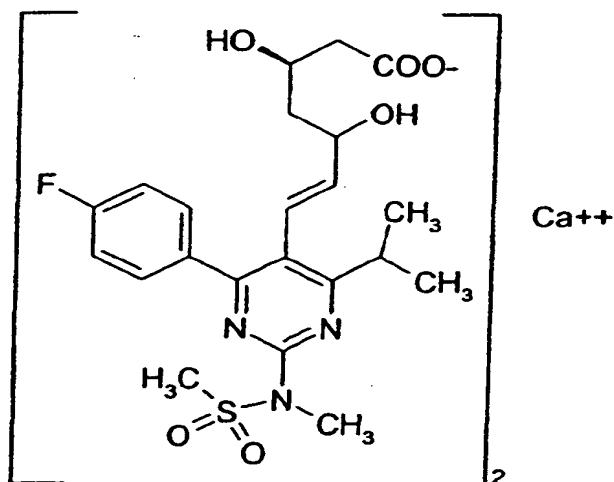
INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2004/003487

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The invention relates to processes for the preparation of amorphous rosuvastatin calcium. More particularly, it relates to the preparation of pure amorphous rosuvastatin calcium and pharmaceutical compositions that include the pure amorphous rosuvastatin calcium. The invention also relates to use of said compositions for treating hyperlipidemia, hypercholesterolemia, and atherosclerosis.



INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB2004/003487

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D239/42 A61K31/505 A61P3/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/60804 A (TAYLOR NIGEL PHILIP ; ASTRAZENECA UK LTD (GB); SHIONOGI & CO (JP); OKA) 23 August 2001 (2001-08-23) cited in the application page 2, line 23 - line 27 page 6, line 24 - line 29; example 10 -----	1-54
X	WO 03/016317 A (NIDDAM-HILDESHEIM VALERIE ; TEVA PHARMA (IL); LIDOR-HADAS RAMI (IL); L) 27 February 2003 (2003-02-27) examples 7,8 -----	1-54
A	US 5 260 440 A (HIRAI KENTARO ET AL) 9 November 1993 (1993-11-09) cited in the application column 4, lines 11-13 ----- -/--	1-54

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *G* document member of the same patent family

Date of the actual completion of the international search

14 January 2005

Date of mailing of the international search report

25/01/2005

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/IB2004/003487

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>HANCOCK B C ET AL: "CHARACTERISTICS AND SIGNIFICANCE OF THE AMORPHOUS STATE IN PHARMACEUTICAL SYSTEMS" JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN PHARMACEUTICAL ASSOCIATION. WASHINGTON, US, vol. 86, no. 1, January 1997 (1997-01), pages 1-12, XP000929450 ISSN: 0022-3549 paragraph '0001!</p> <p>-----</p>	1-54

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2004/003487

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 54 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB2004/003487

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0160804	A	23-08-2001	AU 775569 B2	05-08-2004
			AU 3208401 A	27-08-2001
			BG 106969 A	30-04-2003
			BR 0108378 A	11-03-2003
			CA 2397450 A1	23-08-2001
			CN 1418198 T	14-05-2003
			CZ 20022754 A3	13-11-2002
			EE 200200445 A	15-12-2003
			EP 1263739 A1	11-12-2002
			WO 0160804 A1	23-08-2001
			HU 0204051 A2	28-05-2003
			JP 2003523334 T	05-08-2003
			NO 20023853 A	14-08-2002
			NZ 520032 A	26-03-2004
			PL 356472 A1	28-06-2004
			SK 11742002 A3	04-02-2003
			US 2003045718 A1	06-03-2003
			ZA 200205331 A	03-10-2003
WO 03016317	A	27-02-2003	US 2002099224 A1	25-07-2002
			CA 2450820 A1	27-02-2003
			EP 1425287 A1	09-06-2004
			HR 20040255 A2	31-08-2004
			TR 200302281 T2	21-09-2004
			WO 03016317 A1	27-02-2003
			US 2003114685 A1	19-06-2003
			US 2004176615 A1	09-09-2004
US 5260440	A	09-11-1993	AT 197149 T	15-11-2000
			CA 2072945 A1	02-01-1993
			CY 2226 A	18-04-2003
			DE 69231530 D1	30-11-2000
			DE 69231530 T2	13-06-2001
			DK 521471 T3	05-02-2001
			EP 0521471 A1	07-01-1993
			ES 2153824 T3	16-03-2001
			GR 3035189 T3	30-04-2001
			HK 1011986 A1	13-07-2001
			HU 220624 B1	28-03-2002
			HU 61531 A2	28-01-1993
			JP 2648897 B2	03-09-1997
			JP 5178841 A	20-07-1993
			KR 9605951 B1	06-05-1996
			LU 91042 A9	24-11-2003
			NL 300125 I1	01-07-2003
			PT 521471 T	30-04-2001
			US RE37314 E1	07-08-2001